SEP 1 2 2000

K002044

Ophthalmoscope 510(k)
Magna Fortis Corporation

SECTION 2 – 510(k) SUMMARY

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Applicant:

Magna Fortis Corp.
13606 NE 20th St.
Bellevue, WA 98033

1-425-747-9851

Contact: Mark Werblud

1) DESCRIPTION OF DEVICE: The Magna Fortis Ophthalmoscope Kit is a battery powered hand held instrument made of metal and plastic along with adapters so that the unit can be used to examine the ear and the oral cavity.

2) STATEMENT OF INTENDED USED: Stone Instrument Ophthalmoscope is a battery powered hand held device containing illumination and viewing optics to examine the cornea, aqueous, lens, vitreous, and the retina of the eye.

3) Name of Device:

Common or Usual Name: Ophthalmoscope

Classification Name: Ophthalmoscope

4) Substantial Equivalence:

This device is substantially equivalent to the Riester Ophthalmoscope in both design, materials and intended use.

5) Safety and effectiveness:

The device has been tested and complies with ISO 10942 direct ophthalmoscopes and Standard IEC 60601-I electrical safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 2 2000

Mr. Mark Werblud
General Manager
MAGNA FORTIS CORPORATION
13606 NE, 20TH # 107
Bellevue, WA 98033

Re: K002044
Trade Name: Magna Fortis Ophthalmoscope Diagnostic Kit
Regulatory Class: II
Product Code: 86 HLJ, 77ERA, 77EOB, 73 CCW
Regulation: 886.1120 (Ophthalmoscope Kit)
Dated: August 16, 2000
Received: August 18, 2000

Dear Mr.Werblud:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) NUMBER K002044

DEVICE NAME: Magna Fortis Ophthalmoscope

INDICATIONS FOR USE: The Magna Fortis Ophthalmoscope is indicated for the examination of the cornea, aqueous, lens, vitreous and retina of the eye. The Otoscope adapter is used to examine the ear canal and drum. The nasopharyngoscope is used to examine the nasal passages. The bent angle adapter is used to examine the oral cavity.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ OR Over-The Counter-Use____
Per 21 CFE 801.109 (Options Format 1-2-96)

Denise L. McCarthy
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K002044